PUBLIC HEALTH COUNCIL

Meeting of the Public Health Council, Tuesday, September 24, 2002, 10:00 a.m., Massachusetts Department of Public Health, 250 Washington Street, Boston, Massachusetts. Public Health Council Members present were: Dr. Howard Koh (Chairman), Ms. Phyllis Cudmore, Mr. George Manthala, Ms. Shane Kearney Masaschi, Ms. Maureen Pompeo, Ms. Janet Slemenda, Dr. Thomas Sterne, and Dr. Martin Williams. Absent members were: Mr. Benjamin S. Rubin. Also in attendance was Attorney Donna Levin, General Counsel.

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Chairman Koh announced that notices of the meeting had been filed with the Secretary of the Commonwealth and the Executive Office of Administration and Finance, in accordance with the Massachusetts General Laws, Chapter 30A, Section 11A ½.

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The following members of the staff appeared before the Council to discuss and advise on matters pertaining to their particular interests: Dr. Letitia Davis, Director, Occupational Health Surveillance Program, Bureau of Health Statistics, Research and Evaluation; Ms. Joyce James, Director, Ms. Joan Gorga, Program Analyst, Determination of Need Program; Mr. Paul Tierney, Director, Food Protection Program, Division of Food and Drug; Dr. Alfred DeMaria, Assistant Commissioner, Bureau of Communicable Disease Control; Mr. Robert Goldstein, Division of Epidemiology and Immunization; Ms. Gillian Haney, Surveillance Program Manager, Division of Epidemiology and Immunization; and Consulting Attorney Priscilla Fox, Office of the General Counsel.

RECORDS OF THE PUBLIC HEALTH COUNCIL:

Records of the Public Health Council Meetings of June 25, 2002, July 23, 2002, and August 20, 2002 were presented to the Council. After consideration, upon motion made and duly seconded, it was voted (unanimously) to approve Records of the Public Health Council Meetings of June 25, 2002, July 23, 2002 and August 20, 2002.

PERSONNEL ACTIONS:

In a letter dated September 10, 2002, Katherine Domoto, M.D., Associate Executive Director for Medicine, Tewksbury Hospital, Tewksbury, recommended approval of the appointment of Ashima Garg, M.D. to the medical staff of Tewksbury Hospital. Supporting documentation of the appointee's qualifications accompanied the recommendation. After consideration of the appointee's qualifications, upon motion made and duly seconded, it was voted (unanimously): That, in accordance with the recommendation of the Associate Executive Director for Medicine of Tewksbury Hospital, under the authority of the Massachusetts General Laws, Chapter 17,

Section 6, the appointment of Ashima Garg, M.D. to the medical staff of Tewksbury Hospital be approved for a period of two years beginning September 1, 2002 to September 1, 2004.

APPOINTMENT	STATUS/SPECIALTY	MEDICAL LICENSE NO.
Ashima Garg, M.D.	Provisional Consultant Orthopedics	208462

In a letter dated September 9, 2002, Paul D. Romary, Executive Director, Lemuel Shattuck Hospital, Jamaica Plain, recommended approval of an initial appointment of an allied health professional and reappointments to the medical staff of Lemuel Shattuck Hospital. Supporting documentation of the appointees' qualifications accompanied the recommendation. After consideration of the appointees' qualifications, upon motion made and duly seconded, it was voted (unanimously): That, in accordance with the recommendation of the Executive Director of Lemuel Shattuck Hospital, under the authority of the Massachusetts General Laws, Chapter 17, Section 6, the initial appointment and reappointments to the medical and allied health staffs of Lemuel Shattuck Hospital be approved as follows:

APPOINTMENT	STATUS/SPECIALTY	MEDICAL LICENSE NO.
Bridget Doherty, CNS	Psychiatry	160620
REAPPOINTMENTS	**STATUS/SPECIALTY**	**MEDICAL LICENSE NO.**
Kenneth Pariser, M.D.	Active/ Rheumatology	40490
Rafael Altieri, M.D.	Consultant/Radiology	157787
Anjoli Andalkar, M.D.	Active/Pathology	49235
Barbara Maxwell, M.D.	Active/Psychiatry	34716
Maryann Carrazza, D.M.D.	Active/Dentistry	14610
Gina Terenzi, D.M.D.	Consultant/Dentistry	18400
David Tesini, D.M.D.	Consultant/Dentistry	12919
Barry Collet, D.P.M.	Consultant/Podiatry	1489
Sally Guy, CNS	Allied Health Professional/Psychiatry	161055
Betty Morgan, N.P.	Allied Health Professional/Psychiatry	148706

Lemuel Shattuck Hospital also indicated the following resignations:

S. Carolyn Acker, M.D. – Psychiatry; Priscilla Alanguilan, M.D. – Anesthesia; David Fang, D.M.D. – Dentistry; Joseph Nash, D.M.D. - Dentistry; Joseph O'Donnell, D.M.D. - Dentistry; and Ellen Wallace, M.D. – Radiology.

After consideration, upon motion made and duly seconded, it was voted unanimously to approve the following Bylaw change for Lemuel Shattuck Hospital:

Current Bylaw #9.2-1 reads: The current clinical departments are medicine, surgery, dentistry, anesthesia, radiology, pathology, physical medicine and rehabilitation, psychiatry and specialty.

Approved Bylaw #9.2-1 reads: The current clinical departments are medicine, surgery, anesthesia, radiology, pathology, physical medicine and rehabilitation and psychiatry.

STAFF PRESENTATION:

"FATAL OCCUPATIONAL INJURIES IN MASSACHUSETTS, 1991-1999", BY LETITIA DAVIS, ScD, DIRECTOR, OCCUPATIONAL HEALTH SURVEILLANCE PROGRAM, BUREAU OF HEALTH STATISTICS, RESEARCH AND EVALUATION AND TSEQAYE BEKELE, COORDINATOR, MASSACHUSETTS CENSUS OF FATAL OCCUPATIONAL INJURIES, OCCUPATIONAL HEALTH SURVEILLANCE PROGRAM:

Dr. Letitia Davis, said in part, "…I appreciate this opportunity to present findings from our surveillance system for fatal occupational injuries in Massachusetts….I would also like to take a moment to acknowlege the victims that these numbers represent. These are individuals who died doing jobs that enable all of us in this room to live the lives we lead every day. They are the carpenters who build our homes. They are the fishermen who put food on the table. They are the convenience store workers who work alone through the night, who are there when we run out of sandwich bread for the morning. I think it is essential to recognize that the hazards these workers face should not be accepted simply as part of the job. We know there is extensive research that many of these deaths could be prevented through redesigning equipment, redesigning jobs, developing and enforcing safety standards, and educating workers and employers about job risks.
Our work here at the Department, tracking these fatalities, is based on the premise that information about how and where these deaths occur is essential to effectively target these prevention efforts. The Department participates in two federally funded programs to track fatal occupational injuries in the state and the first is known as the Census of Fatal Occupational Injuries, funded by the Bureau of Labor Statistics, whereby we use multiple data sources to identify and document all the fatal occupational injuries in the Commonwealth. We also participate in the Fatality Assessment Control and Evaluation Project, otherwise known as FACE, which is funded by CDC. In this project, we actually go into the work place to conduct research oriented investigations of selected work related fatalities, to identify factors leading to the incidents. We prepare detailed case reports that included recommendations to prevent similar incidents in the future. We work with engineers at UMASS Lowell in developing these recommendations and we prepare these detailed case reports which are disseminated widely to

influence safety throughout the state…Most of the information I will be presenting today is derived from our Census of Fatal Occupational Injuries (CFOI) Program, although some of the findings are also coming from the Fatality Assessment and Control Evaluation (FACE) program, both federally funded."

Dr. Davis continued, "What is Fatal Occupational Injury? What do we count? We count all deaths due to an injury that occurs while a person is either at or traveling for work in Massachusetts. These include events like falls and electrocutions. I also include homicides and suicides at work. We count everyone, including the self-employed and unpaid family members working for family businesses. We do not count fatalities that happen while traveling to and from work. We use multiple data sources. We have some newspaper clipping services. We have a Memorandum of Understanding with OSHA and the Coast Guard. We have police reports and death certificates. We have an 800 24 hour Occupational Fatality Hot Line to receive case reports from medical examiners, town clerks, fire fighters and other first responders in the state. Our methods are straightforward. We look at the number of deaths and we present these by various personal and employment characteristics, such as age, gender, race, industry and occupation…We also compute rates, which are defined as the number of deaths per hundred thousand workers and we generate the employment data from the current population survey. Rates are measures of risk. They are an indicator that a worker is likely to be killed on the job. You can have a small industry with a small number of workers killed, but the risk of any single worker being killed is high. Alternately, you can have a large industry with a relatively large number of workers being killed, and the risk is low. When we use the data to target prevention efforts, we take both the number of fatalities and the rates into account, and some of the rates in this report are based on small numbers. These need to be interpreted with caution."

Dr. Davis said, "During the nine year period, 633 workers were fatally injuried at work in Massachusetts, an average of 70 workers each year, or between one and two workers each week, and the overall fatality rate during this time period was 2.3 per hundred thousand workers. There was no clear cut trend in either number or rate. We had hoped for a downward trend but we had an upsurge in 1999, so we need to wait a few more years to see what is really happening over time. Most of our cases are men, about 93%. When we look age, what we see is that the majority of the victims are killed on the job in the prime of their working lives, which is between 25 and 44 years old. We actually had 6 workers less than 18 years old killed on the job during this time period. Three of them were news carriers who were struck by vehicles when delivering newspapers. The fatality rate increases with age. In the oldest age group, we had 49 cases, but the rate for this oldest age group was actually three times the state average, and about half of the fatalities in this oldest age group are a result of fatal falls, which is more so than it is in the group in general." Some further statistics follow from Dr. Davis's presentation:

- A total of 633 workers died as result of fatal occupational injuries sustained in Massachusetts during 1991-1999 – an average of 70 fatalities a year, between one and two workers each week (1.3 fatalities per week).

- The annual average fatality rate was 2.3 fatalities per 100,000 workers. There was no clear-cut trend in fatality rates over the nine-year period.

- The great majority of victims (93%) were male, and male workers had a much higher rate of fatal occupational injury then female workers.

- The rate of fatal occupational injury increased markedly with the age of the workers.

- Workers of Hispanic origin (regardless of race) had a high rate of fatal occupational injury compared to black and white workers.

- Foreign-born workers accounted for a high proportion of fatal injuries among workers of color and made up a disproportionate share of the victims of workplace homicide.

- Agriculture (excluding Fishing and Forestry) had the highest fatal occupational injury rate, more than five times the average rate for all industry divisions. Two thirds of the 35 fatalities in this industry division involved workers employed in landscaping and horticultural services.

- The construction industry division had both a high number of fatal injuries (136) and the second highest fatal occupational injury rate. More than half of the construction workers fatally injured on the job died as a result of falls.

- The Farming, Forestry and Fishing occupation group had the highest fatality rate, more than thirteen times the average rate for all occupations. Most of the workers in this group (57 of 95) were fishers. Commercial fishing claimed more lives than any other single occupation.

- Fatal occupational injuries due to transportation-related incidents – including land, water, and air transport incidents – lead all event categories. Within this category, highway motor vehicle incidents and water vehicle incidents were the most frequent events resulting in 84 and 51 fatalities respectively.

- Falls to lower levels was the leading single fatal event in Massachusetts, accounting for 118 fatalities.

- A total of 69 government employees died on the job in Massachusetts.

- Self-employed workers had a higher occupational fatality rate (more than twice) than wage and salary workers in Massachusetts.

- Small establishments in Massachusetts (with 19 or fewer employees) had a high fatal occupational injury rate, more than one and a half times the average rate for establishments of all sizes.

- More than 60% of the occupational fatalities were not inspected by OSHA because: (a) they did not fall under OSHA's jurisdiction; or (b) they resulted from events that are not routinely investigated by the agency; or (c) death occurred more than 30 days after the injury.

- Most fatal falls to lower levels (61%, 72 fatalities) occurred in the construction industry division and two-thirds of these occurred in small establishments with 10 or fewer employees.

- The fatal fall rate in construction was as high as sixteen times the average fatal fall rate for all industries.

- Older workers had a six-fold increased risk of fatal falls to lower levels compared to workers of all age groups.

- Work-related homicide was the third leading fatal event, accounting for 82 fatalities.

- Work-related homicides were concentrated in a small number of industries and occupations.

- Male workers had a higher rate of workplace homicide than female workers.

- Homicide was the leading fatal event among black and Hispanic workers.

- Robbery was the leading precipitating circumstance, where motive was known, of work-related homicides.

- Workplace homicides are more likely to result from shooting than non-workplace homicide.

- Most work-related fishing fatalities occurred as a result of sinking or capsizing of fishing vessels.

- Most (61%) fishing fatalities occurred during fall and winter seasons.

- Massachusetts had lower annual fatal occupational injury rates than the nation for each year of the period under consideration. The rate difference was in part explained by the difference in the occupation composition and industry mix of the labor force between Massachusetts and the nation. Low homicide and motor vehicle related death rates in Massachusetts have also contributed to the low fatal injury rate of the state.

- The average age at death was 42.4 years. These fatalities resulted in an average 33 years of potential life lost for each death (number of years before the victim reached age 75) and for a total of 20,724 years of potential life lost over the nine-year period.

- The number of work-related fatalities and fatality rates in Massachusetts fluctuated over time. Except for 1998, the annual number of fatalities ranged between 62 and 86 and the annual fatality rate between 2.0 and 3.0 fatalities per 100,000 workers. The lowest number of fatalities was observed in 1998 and the highest in 1993.

- The great majority (589 workers, 93%) of workers who died due to work-related injuries were men. Female workers accounted for the remaining 44 fatalities (7%).

- The fatal occupational injury rates for male workers were much higher than the rates for female workers for all the years under consideration. The average annual fatal occupational injury rate for the nine-year study period for men was 4.1 fatalities per 100,000 workers, more than thirteen times the rate for women (0.3 per 100,000). These findings are consistent with findings at the national level.

- The difference in fatality rates for men and women is likely in large part due to the fact that more men are employed in high-risk occupations. For example, in 1999, proportionately more men (18%) than women (3%) were employed in two occupation groups with high fatality rates: 75% of female workers compared to 52% of male workers were employed in two occupation groups with low fatality rates: Managerial & Professional Specialty occupations and Technical Sales and Administrative Support occupations.

- Fatal events varied by gender. Highway transportation incidents (16 fatalities, 36%) and homicide (12 fatalities, 27%) were the two leading events for female workers, accounting for 63% of all female fatalities. In contrast, fall to a lower level was the leading event among men (114 fatalities, 20%) followed by homicide (70 fatalities, 12%), and highway transportation incidents (68 fatalities, 12%).

- The average age at death for the nine-year period was 42.4 years, with a range of 9 to 85 years. Most workers (398 fatalities, 63%) who were fatally injured on the job were 45 years old or younger.

- Six workers (1%) were less than 18 years of age. These included: 3 newspaper carriers who were struck by vehicles while delivering papers; a teen worker who was fatally injured when a trench collapsed on him; a teen worker who was crushed by a street sweeper; and another teen worker who committed suicide while at work.

- Forty-nine victims (8%) were 65 years of age or older, and the risk of being fatally injured on the job increased markedly with age. A similar age trend is seen in the national data.

- Fatality rates calculated using number of workers employed underestimate the risks faced by both older (greater than 64 years) and younger (less than 18 years) workers. Workers in both these age groups are more likely to be employed part-time; therefore their rates are higher when actual total work hours are taken into account.

- Fatal events varied by age. Forty-nine percent of the workers 65 years or older (24 fatalities) died as a result of falls compared to 19% (109 fatalities) of workers less than 65 years old.

- Based on data obtained from death certificates for fatally injured workers, 562 workers (89%) were white while 31 (5%) were black and 24 (4%) were of Asian or Pacific Islanders

descent. Thirty-two workers (5%) were of Hispanic origin.

- White workers had lower fatal occupational injury rates than other workers. The rate for black workers was 2.7 fatalities per 100,000 workers compared to a rate of 2.2 fatalities per 100,000 for white workers. Workers of Hispanic Origin had the highest rate of fatal injury (3.3 fatalities per 100,000 workers). Findings are consistent with previous reports that minority workers are disproportionately employed in high-risk jobs.

- Industry divisions in which high numbers of fatal injuries occurred varied by race. A high number of fatal occupational injuries among non-white workers occurred in the Trade Industry whereas a high number of white workers lost their lives in the Construction industry.

- Leading fatal events also varied by race and ethnicity of victims. Falls were the leading event among white workers, while homicide was the leading event among black, Asian, Hispanic workers.

- Transportation related incidents (including land, water and air transport incidents) led all event categories. During the nine-year period, 221 workers (35% of fatalities) died from work-related transportation incidents. Within this category, highway motor vehicle incidents and water vehicle incidents were the most frequent, resulting in 84 and 51 fatalities, respectively. Forty workers were struck by vehicles and 24 died in aircraft crashes.

- Falls, the second leading event category, accounted for one-fifth (133 fatalities, 21%) of all fatal occupational injuries. Within this category, fall to lower levels was the single leading event; sixty percent (71 fatalities) of the falls to lower levels occurred in the construction industry division.

- Assaults and Violent Acts was the third leading event category, accounting for 115 fatalities (18%). Homicide, which is the major single event within this category and the third leading event overall, claimed a total of 82 workers' lives, while suicides and animal attacks accounted for 33 fatalities. In more than two-thirds (68%) of the homicides, firearms were used as a means of assault. Robbery was the primary circumstance in workplace homicides for which information about circumstance was available; 25 out of 51 (49%) of the cases occurred during robbery.

- Contact with objects accounted for the fatalities of 88 workers (14%). Twenty-four victims died after being struck by falling objects such as trees and electrical poles. Another 21 workers died when they were caught in running equipment or machinery. About 61% (54 fatalities) of the 88 fatalities due to contact with objects occurred in the Construction, Manufacturing and Agriculture industries, whereas only 35% of all fatalities occurred in these industries.

- Fifty workers (8%) died from Exposure to Harmful Substances and Environments at their workplaces. Half (25) of them were electrocuted, 15 died from inhaling harmful substances

and 8 died from oxygen deficiency.

- Fires and Explosion events fatally injured 25 workers (4%) during the nine-year period. Fire incidents claimed the lives of 17 workers while 7 workers died from explosions. Ten victims of fire incidents were fire fighters who died in the line of duty due to an injury; six of them died in a single incident.

In closing, Dr. Davis said in part, "…I think the high rates for Hispanic workers is a problem…We have a research project where we are working with community health centers to document the occupational health experience of low income minority workers, and we are also just embarking, through our FACE project, on conducting a work site investigation of all fatalities involving minority and immigrant workers. Young workers are also a priority for us in Massachusetts. We have a surveillance system for non-fatal injuries with youth. The numbers are small, but obviously the tragedy is great in the years of potential life lost. We are going to make young workers a priority for us here at the Department. I think there are a number of outstanding issues that need to be addressed, not only by the Department but with partners throughout the state. Clearly, Commercial Fishing is on the list, our landscapers, workplace homicide, providing for older workers, and we do have an aging work force. The average age of the work force is increasing, so older workers is going to become more and more of an issue; here in Massachusetts, actually, more so than even other parts of the country, and clearly workers in small businesses, and the self-employed really impose significant challenges, and we need to develop innovative strategies to reach workers in these hard to reach populations, whose needs have not been well addressed in the conventional kind of industry-based approaches to occupational safety and health."

Chairman Koh added, "…Let me stress that Dr. Davis is not only a statewide leader, but a national leader, has been promoting awareness on occupational health for many years, and she has pointed out what should be clear to all of us, that most of us spend most of our waking hours at work, so occupational health issues are of utmost relevance to all of us. I also think of that wonderful line from the Healthy People 2010 document, 'the health of the individual is inextricably linked to the health of the community' and we should add especially and including the workforce. When we think of public health in its broadest terms, upholding public health means protecting people not only where they live, but also where they work, and your data shows that very clearly."

Chairman Koh continued, "Just to reiterate some of your main points, Dr. Davis, you stressed that our occupational fatality rate in our state is half of the national average, but that deaths do occur in people who are in the prime of their lives, so there are many years of potential life lost. You have done a very thorough analysis showing opportunity for prevention for commercial fishers, construction workers and landscapers, preventing falls as a priority. If we talk about occupational health in general, we touch on themes of injury prevention, violence prevention, minority health, outreach to multilingual populations, men's health, health and safety of self-employed workers, and elder health. It is very relevant to all of us…." A brief discussion followed.

NO VOTE/INFORMATION ONLY

NOTE: For the record, at this point, the Council heard docket items 5a and 5b out of order as follows:

DETERMINATION OF NEED PROGRAM:

PREVIOUSLY APPROVED DoN PROJECT NO. 4-3966 OF METROWEST MEDICAL CENTER:

Ms. Joan Gorga, Program Analyst, Determination of Need Program, presented the Metrowest Medical Center's request to the Council. She said, "…Last September, staff presented to you the third progress report submitted by Metro West Medical Center and by the Metro West Community Healthcare Coalition regarding the ten conditions of Project No. 4-3966, which was approved by the Council in February 1999. At that time, the Council found that, while Metro West had shown progress in complying with the conditions by working with the Coalition, additional time and attention were necessary to achieve full compliance with the conditions. Staff is pleased to note that there has been progress in the past year, and that the Coalition reports that they have had productive communications with Metro West around the ten conditions. Transportation continues to be a difficult problem to solve, and the Coalition has indicated that, in the absence of a permanent solution, it finds the taxi vouchers used by Metro West an acceptable interim step. The Coalition requests that there be additional emphasis on training and outreach to publicize the vouchers. Cultural competence also continues to be a challenging issue. Discussions in the coming year will include the issue of interpreter continuity of care, as well as a continuing discussion on the development of standards of care for interpreter services. An example of a standard of care would be a measure of the time that the interpreter should be available to the patient. Staff has found that the medical center continues to make progress towards full compliance with the ten conditions of approval….The Coalition has requested that Metro West return to the Public Health Council in one year. Staff recommends that Metro West be directed to submit a further update to the Council in September of 2003 on its progress in complying with all the conditions of its approved DoN Project 4-3966 and that staff be directed to report its findings to the Public Health Council. Staff hopes that the next report will include further progress in the discussion of cultural competence."

Mr. Larry Volkmar, Chief Operating Officer, and Ms. Beth Donnelly, Director, Community Relations, Metro West Medical Center, were available for questions by the Council. Mr. Volkmar noted that they utilize the AT&T Language Line for interpreter services as needed. Mr. Kevin McNamara, of the Metro West Community Healthcare Coalition was present for questions by the Council. No questions asked.

After consideration, upon motion made and duly seconded, it was voted unanimously to approve Staff's recommendation that **MetroWest** be directed to submit a further update to the Council in one year on its progress in complying with all of the conditions of its approved DoN **Project No. 4-3966,** and that staff be directed to report its findings to the Public Health Council.

PLANNED PARENTHOOD LEAGUE OF MASSACHUSETTS, INC. – REQUEST FOR TRANSFER OF SITE OF PLANNED PARENTHOOD OF WESTERN MASSACHUSETTS – A FREESTANDING AMBULATORY SURGERY CLINIC:

Ms. Joyce James, Director, Determination of Need Program, presented the transfer of site request for Planned Parenthood of Western Massachusetts. Ms. James said, "Planned Parenthood League of Massachusetts, Inc. is requesting to transfer its clinic, Planned Parenthood of Western Mass. from its existing site to a proposed site, which is approximately three miles from the existing site in Springfield. We are recommending approval of this request because it meets the Determination of Need criteria review for transfer of site – namely – it does not constitute a substantial change in service, or a substantial capital expenditure. It will also not change the population currently served in the clinic. We did receive some comments from an individual presumably residing in Chicopee. The comments we find were irrelevant to the Determination of Need review criteria and could not be used as a basis for recommendation of denial of the transfer of site. We continue to recommend approval of the transfer."

Staff's analysis indicated the following:

"Planned Parenthood indicates that the proposed 7,991 gross square feet (GSF) at the new site will correct the many physical plant deficiencies of the 4,494 GSF of space currently occupied by the clinic at the existing site and allow the clinic to operate more efficiently. Planned Parenthood states that consistent with DoN Regulations 105 CMR 100.720 (Transfer of Site Procedures), the proposed transfer of site will not result in either a substantial change in service or a substantial capital expenditure. Also consistent with the regulations, the transfer will not change the population served by the clinic, since the proposed site is only three miles from the current site in Springfield so that the clinic will continue to serve the same population. Staff's finds that approval of the proposed transfer of site is warranted under DoN regulation 105 CMR 100.720 (I), for the following reasons: 1) the clinic will continue to provide the same service at the new site as it did at the existing site so there will be no substantial change in service; 2) the proposed capital and operating costs associated with the project are below the Determination of Need expenditure minimums (September 2001 dollars) for clinics and therefore do not constitute a substantial capital expenditure; and 3) the transfer will not substantially change the population served by the clinic, since both the current and proposed sites are in the city of Springfield which is among the cities and towns that accumulatively make up 75% of the clinic's total discharges." It was noted that comments were submitted by Anne L. Fitzpatrick of Chicopee, MA on the proposed transfer of site. The comments indicated that abortion was the focus of the family planning services provided by the clinic and, therefore, the clinic's license should be revoked. In response, staff notes that the comments were not relevant to the DoN Regulation's criteria for a transfer of site and therefore provided no basis for a recommendation of denial of the proposed transfer of site."

After consideration, upon motion made and duly seconded, it was voted: (unanimously) to approve the transfer of site of **Planned Parenthood League of Massachusetts, Inc., d/b/a Planned Parenthood of Western Massachusetts**, from 110 Maple Street, Springfield, MA to 3550 Main Street, Springfield, MA.

PROPOSED REGULATIONS:

INFORMATIONAL BRIEFING ON PROPOSED AMENDMENTS TO 105 CMR 300.000: REPORTABLE DISEASES AND ISOLATION AND QUARANTINE REQUIREMENTS:

Alfred DeMaria, Jr., M.D., Assistant Commissioner, Bureau of Communicable Disease Control, made introductory remarks to the Council. He said in part, "We come before the Council today with the intent to go to hearing on revisions of our Reportable Disease and Isolation Quarantine Regulations, 105 CMR 300.000, which have been revised only twice in the last ten years, once ten years ago in a fairly comprehensive way and then four years ago when we added HIV reporting to the list of Reportable Diseases, which, by the way, has worked out even better than expected."

Mr. Robert S. Goldstein, Director, Division of Epidemiology and Immunization, gave background on the proposed revisions, "…Approximately a year and a half ago the Division of Epidemiology and Immunization convened a Surveillance Advisory Group, that consisted of various representatives from bureaus throughout the Department of Health, local boards of health, and key local health organizations and partners. The committee broke into four subgroups, which dealt with the various concerns and the issues that Gillian Haney will outline. We have received substantive input from all of the working groups and members of the working group, and we are here today in order to present our summary."

Ms. Gillian A. Haney, MPH, Surveillance Program Manager, Division of Epidemiology and Immunization, addressed the Council. She said in part, "…These regulations have been updated to incorporate new federal communicable disease surveillance recommendations, and the latest recommendations for isolation and quarantine."

Description of the proposed revisions to the regulations:

- **General Revisions** have been incorporated throughout the regulations:

1. The reporting requirements now apply to veterinarians and health care providers in general.

2. M.G.L.c.111,SS 1,5,94C,110B and M.G.L.c.111D,S.6, cited as authorizing certain modifications.

3. Specifying to whom reports of disease or illness should be sent (e.g., to the community where the case is diagnosed).

4. How these reports may be sent (by telephone, by facsimile or electronic means).

5. Requiring, when available, the following on each report: name, date of birth, age, sex, address and disease.

6. In certain circumstances, requesting that when the local board of health is unavailable the Department should be contacted directly.

- **Specific Revisions**

300.020: Definitions. The following new terms were defined:

1. Airborne, contact, droplet, enteric, and standard precautions

2. Invasive Infection

3. Laboratory

4. Unusual illness

5. Zoonotic

300.100: Diseases Reportable to local boards of health. Specific demographic information is now requested in each report of disease. The following diseases or conditions were added to the list of diseases or clarification of the reportable event was added. This was done to reflect emerging infectious disease threats, changes in nomenclature, and newly recognized disease presentations.

1. Arbovirus infection, including but not limited to infection caused by dengue virus, Eastern equine encephalitis virus, West Nile virus and yellow fever virus

2. Calicivirus infection, including but not limited to gastroenteritis caused by Norwalk and Norwalk-like viruses

3. Creutzfeldt-Jakob disease

4. Cryptococcosis

5. Cyclosporiasis

6. Ehrlichiosis

7. Food poisoning and toxicity (includes poisoning by mushroom toxins, ciguatera, scombrotoxin, tetrodotoxin, paralytic shellfish toxin and amnesic shellfish toxin, and other toxins)

8. Group A streptococcus, invasive infection

9. Group B streptococcus, invasive infection

10. Guillain Barre Syndrome

11. Haemophilus influenzae, invasive infection

12. Hantavirus infection

13. Influenza

14. Meningitis, bacterial, community-acquired

15. Meningitis, viral (aseptic) and other non-bacterial

16. Meningococcal disease, invasive infection (N. meningitidis)

17. Plague

18. Q Fever

19. Rabies in humans

20. Rickettsialpox

21. Shiga toxin-producing organisms isolated from humans, including enterohemorrhagic E. coli (EHEC)

22. Smallpox

23. Streptococcus pneumoniae, invasive infection

24. Viral hemorrhagic fevers

Kawasaki disease and rabies in animals were removed from the list in line with national recommendations.

300.120: Confidentiality. A new section was added specifying who may have access to confidential records, how such information should be protected and when it may be released.

300.130: Prevention of foodborne Cases of Viral Gastroenteritis. This section, affecting food handling facility employees testing positive for Norwalk or Norwalk-like infection, is designed to prevent foodborne outbreaks.

300.140: Reporting of animal diseases with Zoonotic Potential by Veterinarians. This section was written in coordination with the Department of Food and Agriculture (DFA), Bureau of Animal Health. Veterinarians are required to report any animal disease potentially infectious to humans to the DFA who will then immediately report such cases to the Department. Veterinarians with knowledge of certain zoonotic diseases are required to report directly to the

Department.

300.150: Declaring a disease or condition immediately reportable: Temporary Reporting – This section will allow the immediate reporting of any emerging infectious disease which threatens public health. Reporting may be required for a 12-month period, after which new regulations must be promulgated for inclusion in the list of reportable diseases.

300.170: Laboratory Findings Indicative of Infectious Disease Reportable Directly to the Department of Laboratories. In accordance with M.G.L.c.111D, SS. 6, clinical laboratories are required to report directly to the Department, evidence of infection found in the examination of clinical specimens as necessary to protect the public health. This new section, based on the list of reportable diseases, specifies which organisms should be reported and what information should be included in the report. Following is a list of the organisms, evidence of which is to be reported in the event of human infection:

300.171: Reporting of Antimicrobial Resistant Organisms. In effort to monitor antimicrobial resistance, this new section requires laboratories to report directly to the Department any result indicating antimicrobial resistance (in certain organisms) or resistance of an unexplained or novel nature.

300.180: Diseases Reportable Directly to the Department. The language regarding tuberculosis reporting was expanded to include latent infection (positive tuberculin skin test). In addition to demographics, information regarding treatment and risk of exposure are requested in the report.

300.190: Surveillance and Control of Diseases Dangerous to the Public Health. This new section specifies what the Department and local boards of health may do to conduct surveillance activities necessary to the investigation, control and prevention of diseases dangerous to the public health. These actions are not new in scope and include, but are not limited to, the following:

1. Systematic collection and evaluation of morbidity and mortality reports.

2. Investigation into the existence of diseases dangerous to the public health in order to determine the causes and extent of such diseases and to formulate prevention and control measures

3. Identification of cases and contacts.

4. Counseling and interviewing individuals as appropriate to assist in positive identification of exposed individuals and to develop information relating to the source and spread of illness.

5. Monitoring the medical condition of individuals diagnosed with or exposed to diseases dangerous to the public health.

6. Collection and/or preparation of data concerning the availability and use of vaccines, immune globulins, insecticides and other substances used in disease prevention and control.

7. Collection and/or preparation of data regarding immunity levels in segments of the population and other relevant epidemiological data.

8. Ensuring that diseases dangerous to the public health are subject to the requirements of 105 CMR 300.200 and other proper control measures.

300.191: Access to Medical Records. This new section grants the Department access to medical records and other information necessary to carry out its duties.

300.200: Isolation and Quarantine Requirements. Proposed revisions to the Isolation and Quarantine Requirements are outlined in exhibits A and B.

Standard Precautions: this new subsection recommends that in addition to the specific practices outlined in the Isolation and Quarantine Requirements, standard precautions should be followed when treating all patients and contacts.

In closing, Dr. DeMaria said in part, "…The other thing that we are going to be doing with these regulatory changes is promoting awareness and distributing them through our Health Alert Network, which is part of our Bioterrorism Preparedness and Response Program. It will be piloted in the next few months, but will ultimately link Public Health Safety and Health Care Providers informationally, and also be available as a resource in the informational library for people to tap into. We are hoping to bring all of these things together and incorporate this into our bioterrorism training."

NO VOTE/INFORMATION ONLY

INFORMATIONAL BRIEFING REGARDING AMENDMENTS TO 105 CMR 561.000: MILKBASED FROZEN DESSERTS AND FROZEN DESSERT MIXES:

Mr. Paul Tierney, Director, Food Protection Program, presented regulations 105 CMR 561.000, accompanied by Attorney Priscilla Fox. Mr. Tierney said in part, "We are here to inform the Council that we hope to go to public hearing soon on regulations 105 CMR 561.000 Frozen Desserts and Frozen Dessert Mixes. The current regulations were promulgated many years ago, and they have been comprehensively updated in this proposal." The proposed changes include:

- Exempt non-milk-based frozen desserts that are produced in a freezing/dispensing machine (i.e., slush machine) from the requirement to obtain a license. [A permit would still be required under 105 CMR 590.000: Minimum Sanitation Standards for Food Establishments for the non-milk-based products].
- Appropriate portions of the U.S. Grade "A" Pasteurized Milk Ordinance (PMO) have been incorporated by reference and apply to the wholesale manufacture of frozen desserts. If the plant uses milk-based ingredients from outside the United States, the importer of the

foreign products must ensure that the exporter complies with applicable federal requirements.

- When a known allergen (as specified by the FDA) is an ingredient of a product, the production equipment must be fully flushed and rinsed before another product is processed, or the product containing the allergen may be processed on dedicated equipment.
- A product recall section has been added, based on federal guidelines for product recalls.
- Requirement that each plant have a Sanitation Standard Operating Procedure (SSOP) governing a variety of sanitation issues in the plant.
- Requirement that raw milk and milk products for use in making frozen desserts undergo bacterial and drug residue tests before being used. Finished products must be tested for bacteria, and manufacturers would be required to notify DPH and the local board of health of which certified laboratory performs their testing. Test results for in-state manufacturers would be submitted directly to DPH and the board of health by the laboratory.
- Set standard plate count and coliform standards for two types of finished product: those produced in manufacturing plants and those produced in freezing/dispensing (soft-serve) machines. Aseptically produced frozen desserts would be required to meet federal standards that define commercial sterility.
- Include procedures for actions that must be taken when a product violates a bacterial standard. These procedures are specified in the PMO and are similar to those in DPH's milk regulations, 105 CMR 541.000.
- The administration and enforcement sections of the proposed regulations are modeled on 105 CMR 500.000: Good Manufacturing Practices for Food. The Food Program is working towards conforming these provisions in all of DPH's food regulations, while leaving room for appropriate additions or modifications on a product-by-product basis. The proposed regulations contain procedures for inspection and reinstatement of a license after suspension, similar to the process described in DPH's milk regulations. This procedure is frequently invoked when the suspension was due to violation of bacterial standards.

NO VOTE/INFORMATION ONLY

FINAL REGULATION:

REQUEST FOR FINAL PROMULGATION OF AMENDMENTS TO 105 CMR 570.000: THE MANUFACTURE, COLLECTION, AND BOTTLING OF WATER AND CARBONATED NON-ALCOHOLIC BEVERAGES:

Mr. Paul Tierney, Director, Food Protection Program, presented regulations 105 CMR 570.000, accompanied by Attorney Priscilla Fox. Staff indicated, "The Department of Public Health (DPH) through the Division of Food and Drugs (DFD), is authorized to adopt rules and regulations relative to sanitary conditions, standards and testing requirements, and labeling requirements for bottled water and carbonated non-alcoholic beverages for human consumption. DFD approves sources of water for bottled water, conducts sanitary inspections of Massachusetts bottling plants, issues permits to out-of-state plants that sell their products in the Commonwealth, and advises local boards of health on questions regarding the operation of in-state plants. The regulation governing these activities is entitled 105 CMR 570.000: The Manufacture, Collection and Bottling of Water and Carbonated Non-Alcoholic Beverages."

Staff said further, "Due to the significance and scope of the regulatory changes proposed, DFD is striking the current regulations and replacing them in their entirety. The proposed revisions will bring Massachusetts' regulations into conformance with the U.S. Food and Drug Administration's (FDA) regulations addressing the same issues. The new regulations incorporate by reference FDA's regulation 21 CFR Part 110: Current Good Manufacturing Practice in Manufacturing, Packing and Holding Human Food; the majority of 21 CFR Part 129: Processing and Bottling of Bottled Drinking Water; and the standards of identity for bottled water products in 21 CFR Part 165: Beverages. Through adhering to the relevant sections of these regulations, bottling companies selling products in Massachusetts will be assured that their products meet both state and federal standards."

It was noted that the Department convened an advisory committee consisting of representatives of in-state and out-of-state bottlers of water and carbonated non-alcoholic beverages, local boards of health, the Massachusetts Department of Environmental Protection, and the Senate Committee on Post Audit and Oversight. Committee members provided the DFD with written and oral comments, many of which were incorporated into the amended regulation. A public hearing was advertised and held on June 26, 2002. Comments were received from eight parties during the hearing.

Changes made to the revisions of 105 CMR 570.000 based upon public hearing testimony:

- The definition of and labeling requirements for "natural water" were deleted, because evolving water treatment technology makes it difficult for industry to comply with, and consumers to rely on, the term "natural". Deleting the term does not affect the protection of public health.

- The requirement that the bottler include the state or local permit number on the product's label was deleted. Such a requirement provides no guarantee that the company's permit is current, and it would be cumbersome for bottlers. Instead, all bottlers that have a Massachusetts permit will be listed on a Department website, and the list will be updated frequently.

- The prohibition on the use of bottling equipment (except filling equipment, which may be used after being thoroughly sanitized) for fat or protein containing food was replaced with a prohibition on the use of such equipment for dairy products and non-beverage foods. The fat

or protein prohibition was too broad and may have unintentionally prohibited the use of certain harmless ingredients.

- The time limit for notification of DPH upon a change of ownership of a bottling plant was increased from 48 hours to 10 days. This change will be easier for the industry to comply with and will not compromise public health.

The significant provisions of the revision to 105 CMR 570.000 follow:

- Adoption of Federal Regulation 21 CFR Part 110: Part 110 is the federal regulation that establishes good manufacturing practices for food products. Because Part 110 establishes a national baseline for sanitary procedures, DPH has adopted this regulation in recent years every time it has revised particular regulations regarding processing of various types of food. This allows Massachusetts-based firms to operate under consistent state and federal regulations.
- Adoption of the majority of Federal Regulation 21 CFR Part 129: Part 129 is the federal regulation governing the processing and bottling of bottled drinking water. DPH proposes to adopt the following portions of this regulation: General Provisions; Equipment; Production and Process Controls; and the majority of the Buildings and Facilities section. Again, this will allow Massachusetts firms to operate under consistent state and federal regulations.
- Adoption of portions of Federal Regulation 21 CFR Part 165: Among other things, Part 165 establishes standards of identity for bottled water products. Standards of identity govern how products must be labeled. Because Massachusetts is preempted by federal law from adopting different standards of identity for products for which a federal standard exists, the new regulations adopt all standards of identity in Part 165.
- Product recall: A product recall section has been added, setting forth procedures that bottlers must follow when there is reason to recall a marketed product. By including cross-references to federal recall requirements, this section ensures that all recalls will be carried out under complementary procedures.
- General Administration and Enforcement: These sections provide bottlers with specific requirements for permitting and approval, which are similar to the administration and enforcement provisions of other food regulations enforced by DFD. The sections provide a number of options by which resolution of compliance issues can be achieved, and they ensure that industry's due process rights are protected.

After consideration, upon motion made and duly seconded, it was voted: (unanimously) to approve the request for **Promulgation of Revisions to 105 CMR 570.000: The Manufacture, Collection and Bottling of Water and Carbonated Non-Alcoholic Beverages**; that a copy be forwarded to the Secretary of the Commonwealth; and that a copy be attached and made a part of this record as **Exhibit Number 14,738.**

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The meeting adjourned at 11:10 a.m.

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Howard K. Koh, M.D., M.P.H.
Chairman

LMH/lmh